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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,659	10/05/2005	Yoshiji Yamada	050174	9383

21874 7590 06/12/2008

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
06/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,659	YAMADA ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008 and 28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *2 and 4-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☒ Claim(s) *1 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0305;0405;1205;0308*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a 371 of PCT/JP03/12052, filed September 22, 2003. It is noted that an English language translation of the International Search Report for PCT/JP03/12052 has been received and considered.

Election/Restrictions

2. Applicant's election of Group I, claims 1 and 3, in the reply filed on February 6, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 2 and 4-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 6, 2008.

4. Regarding the further restriction requirement applicable to Group I (see page 4 of the Office action mailed January 10, 2008), Applicant's election with traverse of the polymorphism combination of (1), (2), and (3) in the reply filed on February 6, 2008 is acknowledged. The traversal is on the ground(s) that "the inventions are not independent" and that a "comprehensive search of the art...would encompass any combination of any of the selected genes, e.g. (1) and (2), or each of (1), (2), and (3) alone." This argument has been fully considered but is not persuasive. It is noted that the instant application is a 371 of a PCT application, and was restricted because the various combinations encompassed by the claims are not "of a similar nature" and lack a special technical feature under PCT Rule 13.2, as discussed at page 4 of the Office

action of January 10, 2008. Applicants' traversal does not address the basis of the restriction, and is not persuasive with regard to the issue of unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

5. Polymorphism combinations other than the combination of the three polymorphisms of (1)-(3) set forth in claims 1 and 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement with regard to the various combinations of polymorphisms encompassed by the claims in the reply filed on February 6, 2008.

Information Disclosure Statement

6. The information disclosure statement filed March 22, 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Accordingly, references AF, AH, and AJ have not been considered; however, the English language documents that were also cited and identified by applicant as "corresponding" to the above noted references (AE, AG, and AA/AI, respectively) have been considered. With regard to reference AG, it is noted that only the English abstract provided has been considered.

7. The information disclosure statement filed April 27, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all

other information or that portion which caused it to be listed. Particularly, a portion of reference BA is cut off and not legible, and reference BL is missing; thus, those references could not be considered.

8. With regard to the information disclosure statement filed December 12, 2005, it is noted that only the abstract of reference AI is in English; accordingly, only the abstract could be considered.

9. With regard to the information disclosure statement filed March 28, 2008, reference CA was crossed through because a complete citation for the reference was not provided and is not available (due to, e.g., the lack of a publication date); however, the material provided has been considered by the examiner.

Claim Objections

10. Claims 1 and 3 are objected to because of the following informalities: the claims encompass non-elected subject matter (specifically, the claims recite the non-elected polymorphism of item (4), and are not limited to the elected combination of all three of polymorphisms (1)-(3)). The claims should be amended such that they are directed to the elected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because it is not clear whether the claim is drawn to a method "for diagnosing the risk for hypertension," as set forth in the preamble of the claim, or to a method in which "a genetic risk for hypertension" is merely "assessed," as set forth in the final process step. The language of the claim does not make clear how or even whether risk (or "genetic risk") for hypertension is actually diagnosed, or make clear how "assessing" a genetic risk for hypertension relates to the "diagnosing" of the claim preamble. Clarification is required.

Claim Rejections - 35 USC § 112, first paragraph

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of genotyping a human subject by analyzing the 3 polymorphisms of the elected combination in a nucleic acid sample from a human subject, and for methods of diagnosing hypertension risk in which the combination of GpIa A1648G, CCR2 G190A, and ApoCIII C1100T polymorphisms are detected as being indicative of hypertension risk in human male subjects, does not reasonably provide enablement for methods of genotyping any type of nucleic acid sample, or for methods of diagnosing hypertension risk in subjects other than human

males. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (*MPEP* 2164.01(a)).

Claim 1 is drawn to a method for "detecting the genotype in a nucleic acid sample" comprising analyzing two or more of the polymorphisms set forth in the claim. Claim 3 is drawn to a method "for diagnosing the risk of hypertension' comprising "analyzing" as in claim 1, as well as additional steps of "determining" the genotype of the sample using the polymorphism information obtaining in the "analyzing" step, and "assessing, based on the genotype determined, a genetic risk for hypertension." It is again noted that applicant elected the combination of polymorphisms corresponding to all three of (1)-(3) in claims 1 and 3, and that other polymorphism combinations are withdrawn from consideration.

It is unpredictable as to whether one of skill in the art could use applicants' invention in a manner reasonably commensurate with the claims. First, each of claims 1 and 3 encompass detecting/determining a genotype for each of a "polymorphism at the base number position 1648 of the glycoprotein Ia gene" (hereinafter referred to as the "GpIa 1648" polymorphism), a "polymorphism at the base number position 190 of the chemokine receptor 2 gene" (hereinafter referred to as the "CCR2 190 polymorphism"), and a "polymorphism at the base number position 1100 of the apolipoprotein C-III gene" (hereinafter referred to as the "ApoCIII 1100" polymorphism). Thus, in the context of the instant invention, determination of a genotype requires the existence of more than one allele for each position being analyzed, in order that a genotype may be established for the sample being assayed. The specification teaches that each of the polymorphisms of the claims exist in human genes (see, e.g., page 7, line 36-page 8, line 7; page 11, line 24-page 12, line 9; and Examples 2-3). Similarly, the prior art teaches that each of these polymorphisms is a well-known human polymorphism identified using the same numbering system employed by applicants; see, e.g., Yamada et al (N Engl J. Med 347(24):1916-1923 [12/2002]) and Izawa et al (Hypertension 41:1035-1040 [3/2003]) regarding all 3 polymorphisms, as well as Kroll et al (Thromb Haemost 83:392-396 [3/2000]) regarding the GpIa 1648 polymorphism, Mettimano et al (British Journal of Biomedical Sciences 60(1):19-21 [4/2003]) and Gonzalez et al (Genes and Immunity 2:191-195 [6/2001]) regarding the CCR2 190 polymorphism, and Groenendijk et al (Journal of Lipid Research 42:188-194 [2/2001]) and Peacock et al (Genetic Epidemiology 14:265-282 [1997]) regarding the ApoCIII

1100 polymorphism. However, the instant claims encompass genotyping any type of nucleic acid sample, while the specification and the prior art only establish the existence of the relevant polymorphisms in human nucleic acids. It is unknown and unpredictable as to whether the polymorphisms of the claims may be analyzed or identified in samples other than samples from human subjects so as to successfully determine a "genotype" for the sample. As the techniques required to carry out genotyping are routine in the art, and the skill level of one of ordinary skill in the art is high, it would clearly be within the ability of one skilled in the relevant art to, e.g., conduct further experimentation aimed at determining whether the polymorphisms of the claims exist in other organisms. However, the outcome of such experimentation cannot be predicted, such that it is unknown as to whether even an infinite amount of experimentation would be sufficient to allow a skilled artisan to practice the claimed invention on any nucleic acid sample other than a human sample. Accordingly, it would clearly require undue experimentation to use applicants' invention in a manner commensurate with the instant claims.

With further regard to claim 3, the claim additional requires "diagnosing the risk of hypertension" and an additional method step of "assessing, based on the genotype determined, a genetic risk for hypertension." The specification provides evidence that 4 particular polymorphisms, including GpIa A1648G, CCR2 G190A, and ApoCIII C1100T, were significantly associated with hypertension risk in Japanese males (see Example 3). The specification also teaches that 4 different polymorphisms were found to be significantly associated with hypertension risk in Japanese females (Example 3). The

specification is silent with regard to any association between the polymorphisms encompassed by claim 3 and hypertension in any type of non-human subject, and is also silent with regard to the existence of variants other than A or G at GpIa 1648, G or A at CCR2 190, and C or T at ApoCIII 1100. Accordingly, while the teachings of the specification would enable one of skill in the art to diagnose hypertension risk in a Japanese male subject by detecting the combination of GpIa A1648G, CCR2 G190A, and ApoCIII C1100T polymorphisms in a nucleic acid sample from the subject, the teachings of the specification are not enabling with regard to other types of subjects, or with regard to a relationship between hypertension risk and variants at GpIa 1648, CCR2 190, or ApoCIII 1100 other than the specific ones noted above. Lacking guidance from the specification, one of skill in the art may looking to the teachings of the prior art for further guidance with regard to the enablement of a claimed invention. In the instant case, the data of Izawa et al (Hypertension 41:1035-1040 [3/2003]) appears to be the same data reported in the instant specification, and is enabling to the same extent as the guidance of the specification. With regard to the GpIa 1648 and ApoCIII 1100 polymorphisms, the prior art is silent with regard to any association between any variants at either of these positions and hypertension in any kind of subject. Mettimano et al (British Journal of Bioscience 60(1):19-21 [4/2003]) teach that CCR2 G190A was found to be significantly associated with essential hypertension in a group of hypertensive subjects as compared to an age-matched control group of Caucasian subjects (see entire reference, particular page 20). Mettimano et al do not make reference to either the ethnicity or sex of the group of hypertensive subjects analyzed;

however, given that Mettimano et al establish a relationship between the G190A CCR2 polymorphism and hypertension in a different group than that examined by applicants, and given there is no teaching in the prior art that would lead one of skill in the art to conclude that the findings of applicants and of Mettimano et al with the CCR2 polymorphism would not apply to other populations of male subjects, the preponderance of the evidence supports a conclusion that applicants' claimed invention is enabled with respect to human male subjects in general. However, given that applicants' own specification teaches away from enablement with respect to female subjects, and because Mettimano et al are silent with regard to the sex of the subjects studied, one of skill in the art would not expect to be able to diagnose hypertension in a female subject by analyzing the GpIa A1648G, CCR2 G190A, and ApoCIII C1100T polymorphisms. Given the high skill level of one skilled in the relevant, it is within the ability of such an artisan to conduct further experimentation aimed at determining whether, e.g., there are other populations or types of subjects other than human males in which the claimed combination of polymorphisms exists and is associated with hypertension. However, the outcome of such experimentation cannot be known, and it is unknown as to whether any quantity of experimentation would actually be sufficient to more broadly enable the claims. Accordingly, while the teachings of the specification and of the prior art are enabling with regard to methods in which the combination of GpIa A1648G, CCR2 G190A, and ApoCIII C1100T polymorphisms are detected as being indicative of hypertension risk in human male subjects, it would require undue experimentation to use applicants' invention in a manner commensurate with claim 3.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Yamada et al (New England Journal of Medicine, 347(24):1916-1923 and supplementary material [12/2002]; cited in the IDS of March 22, 2005).

It is noted that the inventive entity of the instant application is distinct from the authorship of the Yamada et al reference and that the Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. This rejection may be overcome by, e.g., the filing of a Katz-type declaration or by establishing priority of the invention to September 25, 2002 by filing a certified translation of applicants' priority document.

Yamada et al disclose analyzing nucleic acid samples obtained from human subjects and determining the genotypes with respect to a multitude of different polymorphisms for each sample (see entire reference, particularly the description of the "genotyping of polymorphisms" methodology at page 1917). The polymorphisms analyzed by Yamada et al include the A1648G (Lys505Glu) polymorphism of the glycoprotein Ia gene, the G190A (Val64Ile) polymorphism of the chemokine receptor 2

gene, and the C1100T polymorphism of the apolipoprotein CIII gene (see Table 1). Accordingly, Yamada et al anticipate claim 1.

17. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Izawa et al (Hypertension 41:1035-1040 [published online March 2003]).

It is noted that the inventive entity of the instant application is distinct from the authorship of the Izawa et al reference and that the Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. This rejection may be overcome by, e.g., the filing of a Katz-type declaration or by establishing priority of the invention to September 25, 2002 by filing a certified translation of applicants' priority document.

Izawa et al disclose analyzing nucleic acid samples obtained from human subjects and determining the genotypes with respect to a multitude of different polymorphisms for each sample (see entire reference, particularly the description of the "genotyping of SNPs" methodology at page 10367). The polymorphisms analyzed by Izawa et al include the A1648G (Lys505Glu) polymorphism of the glycoprotein Ia gene, the G190A (Val64Ile) polymorphism of the chemokine receptor 2 gene, and the C1100T polymorphism of the apolipoprotein CIII gene (see Table 1). Accordingly, Izawa et al anticipate claim 1. With further regard to claim 3, Izawa et al state that "2 different sets of 4 of the 33 SNPs examined were associated with hypertension in men and women on the basis of a probability value <0.05 in either a dominant, recessive, or additive genetic model (see page 1036, right column), and the list of 4 SNPs "Associated with

Hypertension" in men presented in Table 3 (page 1037) includes the 3 polymorphisms noted above (i.e., the 3 polymorphisms of the elected invention). Accordingly, Izawa et al disclose a step of "assessing, based on the genotype determined, a genetic risk for hypertension," as required by the claims. With further regard to the statement in the claim preamble that the method is one "for diagnosing the risk of hypertension", it is noted that the instant claim does not include an actual method step of "diagnosing." Rather, this recitation merely sets forth the intended use of the method, and does not result in any manipulative difference between the claimed invention and the method of Izawa et al, such that the recitation "for diagnosing the risk of hypertension" is not considered a claim limitation and is of no significance to claim construction. See *MPEP* 2111.02. Thus, Izawa et al also anticipate claim 3.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al (Thromb Haemost 83:392-396 [2000]; cited in the IDS of April 27, 2005) in view of Groenendijk et al (Journal of Lipid Research 42:188-194 [2/2001]) and Gonzalez et al (Genes and Immunity 2:191-195 [6/2001]).

The claim is drawn to a method for "detecting the genotype in a nucleic acid sample" comprising analyzing two or more of the polymorphisms set forth in claim 1. It is again noted that applicant elected the combination of polymorphisms corresponding to numbers (1)-(3) in claim 1, and that the polymorphism of (4) is withdrawn from consideration.

Kroll et al disclose analyzing the Gpla gene A1648G polymorphism (which constitutes a "polymorphism at the base number position 1648 of the glycoprotein Ia gene) in different subpopulations of a group of human subjects, and disclose that the A1648 variant is associated with the presence and extent of coronary artery disease in low risk patient subgroups (see entire reference, particularly page 394 and Table 3).

Groenendijk et al disclose analyzing the apoC-III gene C1100T polymorphism (which constitutes a "polymorphism at the base number position 1100 of the apolipoprotein C-III gene) in different subpopulations of human subjects, and disclose that the T1100 variant is associated with elevated plasma triglycerides (see entire reference, particularly page 190, right column), and also that this variant has been associated with atherosclerosis (see page 188, right column).

Gonzalez et al disclose analyzing the CCR2 gene polymorphism encoding V64I (i.e., the G190A polymorphism, which constitutes a "polymorphism at the base number position 190 of the chemokine receptor 2 gene) in different subpopulations of human subjects, and disclose that while this polymorphism was not found to be associated with myocardial infarction, CCR2 is known to be important in the "initiation of atherosclerosis" (see entire reference, particularly page 193, left column).

The Kroll et al, Groenendijk et al and Gonzalez et al references thus each disclose genotyping one of the polymorphisms of the elected invention in the context of investigating factors contributing to diseases of the circulatory system. The prior art does not disclose genotyping these three polymorphisms together in a single method, as required by the instant claim. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have done so. Each of the references discloses the analysis of multiple different polymorphisms in investigating the association of genotypes and haplotypes with disease (see, e.g., Kroll et al, page 392, right column; Groenendijk et al, pages 190-191; Gonzalez et al, page 194), and Gonzalez et al further suggest that polymorphisms in genes other than those analyzed may contribute to disease susceptibility or progression (see page 194, left column). An ordinary artisan would have been motivated to have analyzed together any group of polymorphisms with known or suspected associations with one or more diseases of the circulatory system, including those of the instant claim, for the advantage of, and to achieve the predictable result of, gathering further information with respect to haplotypes and genotypes associated with such diseases.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634